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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,519	01/03/2002	Daniel Benjamin	ORT-1550	7332
27777	7590	12/15/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			COOK, LISA V	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/037,519

Applicant(s)

BENJAMIN ET AL.

Examiner

Lisa V. Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/14/02 - 5/13/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicants' election with traverse of Group I (claims 1-4) in the response filed 11/19/04 is acknowledged. Applicant contends that group II (claims 5-8) should be examined with group I because they utilize the same reagents and would not impose a serious burden on the examiner. The traversal on the ground(s) "that the examiner has not shown that a serious burden would be required to examine the claims of group I and group II", is not found convincing.

This is not found persuasive because MPEP § 808.02 recites:

Where related inventions as claimed are shown to be distinct under the criteria of MPEP § 806.05(c)- § 806.05(i), the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: (A) Separate classification thereof, (B) A separate status in the art when they are classified together, or (C) A different field of search.

This argument was carefully considered but not found persuasive because Groups I and II do not employ the same reagents therein the search for the two methods is not totally co-extensive. Specifically, the Groups are patentable distinct and require separate fields of search because group I uses an aggregated alpha synuclein solution while group II uses a non aggregated alpha synuclein (which is not utilized in group I). Accordingly the groups were not rejoined.

2. The Restriction Requirement is still deemed proper and is therefore made **FINAL**.

3. Currently, claims 1-8 are subject to Restriction and Election Requirement. Claims 5-8 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as claims drawn to a non-elected invention. Claims 1-4 are under examination.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.

5. The information disclosure statement filed 14 May 2002 has been considered as to the merits before First Action.

6. The information disclosure statement filed 13 May 2003 has been considered as to the merits before First Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1 the use of the term “reduction in fluorescence” is vague and indefinite because it is not clear when or if an initial fluorescence measurement was conducted. It is suggested that the claim clearly recite the detection of fluorescence as a result of aggregated alpha synuclein solution and Thioflavin T without compound reduction and/or prevention so that a reduced measurement can be detected.

B. Claim 3 is vague because it is not clear as to what limitation “enhancing peptide” encompasses. The phrase has not been defined in the disclosure or the claim. As recited the meets and bounds of the claim cannot be determined. If it is applicant’s intent to merely claim SEQ ID NO:3 or SEQ ID NO:4 then that should be clearly set forth in the claim. If some other attribute will be added to the referenced sequences, that attribute is unclear. Appropriate correction is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biere et al. (US Patent #6,184,351) in view of Murray et al. (Society for Neuroscience Abstracts, Vol.26, No.1-2, 2000 – Abstract No.-84.10).

Biere et al. teach aggregation assays measuring aggregated human recombinant NACP/ α -synuclein (column 3 lines 3-18 and Gene Core sequence search – result 2) in the presence of a test compound. In Biere's assay a pre aggregated alpha synuclein solution is added to the test sample and the change in fluorescent detection was measured at 280 nm - wavelength (as an indication of change in aggregation). See figure 3, column 2 lines 38-43, and column 8 lines 26-27.

The human recombinant NACP/ α -synuclein composition taught by Biere et al. read on claims 3 and 4 because the claims recite compositions comprising residues 61-90 of alpha synuclein = SEQ ID NO:3 or SEQ ID NO:4. Therefore, the full length 140 amino acid NACP/ α -synuclein of Biere et al. includes SEQ ID NO:3 and SEQ ID NO:4.

Biere et al. differ from the instant invention in not specifically teaching fluorescent detection with Thioflavin T (Thio T).

However, Murray et al. disclose an aggregation system detecting compounds that inhibit alpha synuclein aggregation. The results were detected via Thioflavin T. See abstract.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention utilize Thioflavin-T in the pre-aggregated alpha synuclein fluorescent detection method taught by Biere et al. because Murray et al. taught that Thioflavin-T appeared to compete with test compounds to inhibit alpha syn aggregation and this could be monitored by the fluorometry assay but not by centrifugation. See abstract. One of ordinary skill in the art would have been motivated to employ Thioflavin-T along with a test compound in a competitive method so that Thio T would serve not only as a positive marker (complete inhibition) but could also provide information of the test compounds interaction when other inhibitors are present. This would prove valuable in finding compounds to treating illnesses exhibiting alpha syn aggregation (Parkinson disease). See Murray et al. abstract.

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12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



Lisa V. Cook

Remsen 3C-59

(571) 272-0816

12/10/04



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

12/11/04